Task Force on Research Specific to Pregnant Women and Lactating Women

Meeting

February 3, 2020

The Task Force on Research Specific to Pregnant Women and Lactating Women (Task Force or PRGLAC) convened its first meeting of 2020 on February 3, at the National Institutes of Health (NIH), 6710B Rockledge Drive, Bethesda, Maryland. In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Interested individuals could attend in person by registering in advance or by viewing the meeting online by NIH videocast. A video archive is available at: https://videocast.nih.gov/summary.asp?live=35498&bhcp=1.

Task Force members present:

- Diana Bianchi, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), Chair
- Shelli Avenevoli, Ph.D., National Institute of Mental Health (NIMH)
- Karin Bok, Ph.D., M.S., National Institute of Allergy and Infectious Diseases (NIAID)
- Andrew Bremer, M.D., Ph.D., NICHD
- Christina Bucci-Rechtweg, M.D., Novartis Pharmaceuticals Corporation
- Camille Fabiyi, Ph.D., M.P.H., Agency for Healthcare Research and Quality (AHRQ)
- Susan Givens, R.N., M.P.H., March of Dimes
- Elena Gorodetsky, M.D., Ph.D., Office of Research on Women's Health, NIH
- Kristi Lengyel, M.B.A., UCB Inc.
- Linda Lipson, M.A., retired, Department of Veterans Affairs (VA)
- Aaron Lopata, M.D., M.P.P., Health Research and Services Administration (HRSA)
- Joan Nagel, M.D., M.P.H., National Center for Advancing Translational Sciences (NCATS)
- Voula Osganian, M.D., Sc.D., National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- Jeanna Piper, M.D., NIAID
- Jennita Reefhuis, Ph.D., Centers for Disease Control and Prevention (CDC)
- Jeanne Sheffield, M.D., Johns Hopkins University
- Diane Spatz, Ph.D., University of Pennsylvania
- Robert Ternik, Ph.D., Eli Lilly and Company
- Kaveeta Vasisht, M.D., Pharm.D., Food and Drug Administration (FDA)
- Wendy Weber, M.D., Ph.D., M.P.H., National Institute of Complementary and Integrative Health (NCCIH)

Executive Secretary Lisa Kaeser, J.D., was also present.

Task Force members absent:

- Dorothy Fink, M.D., Office of Women's Health, Department of Health and Human Services (HHS)
- Melissa Gorman, M.S.N., RN-BC, CCRN, Shriners Hospital for Children
- Brigette Jones, M.D., University of Missouri-Kansas City
- Victoria Pemberton, M.S., RNC, CCRC, National Heart, Lung, and Blood Institute (NHLBI)

The following Task Force members resigned prior to the meeting:

- Terry Adirim, M.D., M.P.H., Department of Defense
- Lois Tschetter, Ed.D., RN, IBCLC, South Dakota State University (retired)
- Steven Foley, M.D., FACOG, Prowers Medical Center

Opening Remarks

Dr. Diana Bianchi welcomed the Task Force to the first meeting of 2020. She expressed appreciation for the service of the three Task Force members who had resigned, and congratulated returning Task Force member, Linda Lipson, on her recent retirement from government service.

Review and Approval of Minutes

Following a motion from Dr. Diane Spatz, and a second from Dr. Jeanne Sheffield, the Task Force unanimously approved the minutes from the August 2019 meeting with no changes.

Updates and Charge for the Meeting

Dr. Bianchi provided a recap of PRGLAC activities since the August 2019 meeting. The Task Force had been divided into four working groups, each assigned to 3-4 recommendations for discussion of the steps needed for implementation. She thanked each of the working groups, including both Task Force members and ad hoc members who had been asked to participate given their areas of expertise. She also noted that PRGLAC members had copies of comments submitted prior to the meeting in their folders; these will be posted on the website. Finally, Dr. Bianchi provided an update on her January 2020 meeting with the ConcePTION/ Innovative Medicines Initiative, a five-year European Union public-private partnership with industry whose goal is to create a centralized database on the safety of medications used during pregnancy and lactation, and a Europe-wide human milk biobank. She noted that there were many areas of potential collaboration with PRGLAC-related activities.

Working Group Presentations

Working Group 4 – Discovery

Drs. Lopata and Gorodetsky presented the findings of Working Group 4, which had been charged with implementation steps for PRGLAC Recommendations 9, 10, and 12.

Rec. 9 – Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women.

To develop programs to drive development of therapeutic products, a prioritization process for research on drugs that are used by pregnant/lactating women would need to be created, beginning with drugs already on the market (generic or on-patent) that are lacking data in labeling for use in pregnant and lactating women. The Working Group was not sure whether additional legislative authority would be required to establish such a process. More broadly, the Group recommended creation of a program similar to the research program at NIH for pediatric drug testing under the Best Pharmaceuticals for Children Act (BPCA).

To mitigate issues of liability and identify incentives for government and industry to conduct research related to discovery and development of therapeutic products for conditions specific to pregnant women and lactating women, the group suggested that a new program be created or mandated that would incorporate elements of the NIH Vaccine Research Center's authority, the Biomedical Advanced Research and Development Authority (BARDA), and the incentive provisions of BPCA.

Rec. 10 – Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research.

The Working Group suggested that clinical researchers be encouraged to develop protocols to test drugs for pregnancy-related conditions, such as preeclampsia and gestational diabetes, and protocols for drugs that might be used by pregnant and lactating women for conditions not related to their reproductive health status.

The group noted that it would be desirable to encourage or require non-governmental study sponsors to submit a PRGLAC assessment and study/plan during drug development that describes available pregnancy and lactation data and plans for how safety and pharmacokinetic data to inform dosing in pregnant women and lactation data will be collected. However, the authority for FDA to implement such a program would likely require a legislative mandate. Such a mandate would also have to address protections from liability for researchers and research participants.

Rec. 12 – Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women.

The Working Group suggested developing a collaborative public-private structure with stakeholders involved in developing platforms for electronic health record (EHR) and organizations that use EHRs to design health record systems to link mother and infant records. To incorporate and to achieve consistency of these linkages datasets, the group recommended to develop an optimal set of variables and make those widely available for systems.

To help augment available data, the group suggested that standardized protocols be developed to link mother /infant EHR linkage datasets and that these datasets should be used to expand our

evidence base for research. One important example of potentially useful linkages is to explore how to link public or private EHR datasets on mothers and infants. Also, the group recommended developing shareable data sources to link mother and infant data. The Working Group would support the legislation if it were deemed necessary to ensure these linkages.

In addition, the Working Group suggested establishing a group of knowledgeable individuals representing the public and private sectors to oversee implementation of the PRGLAC recommendations, once the implementation plan has been published. (Note: An implementation oversight entity was recommended in the 2018 PRGLAC report; this was deferred until the implementation plan has been published, and the current charter extension expires in 2021.)

Discussion

During the initial discussion on Recommendation 12, the group agreed that a set of Common Data Elements would facilitate research in both pregnancy and lactation. Several Task Force members suggested that partnerships with organizations that are already linking data might be a good beginning, such as the PCORI Trust Fund and the VA's Women's Health Research Network, which is planning work with the Department of Defense Birth and Infant Health Research (BIHR) Program and the Naval Health Research Center's Millenium Cohort Study. Another possible source mentioned is the American Association of Colleges of Pharmacy.

The discussion around Recommendations 9 and 10 generated the most conversation, largely around whether the implementation steps put forward by the Working Group were focused less on "discovery" for product development and more on testing drugs currently on the market for use during pregnancy and lactation. The Best Pharmaceuticals for Children Act (BPCA) NIH model is for the latter, while models for product development include the Orphan Drug Act and the FDA's pediatric voucher program. Some concerns were raised about the creation of a new mandate for industry, which would be similar to that required by the Pediatric Research Equity Act.

Common obstacles to testing pharmaceutical therapies include the interpretation of ethical regulations by Institutional Review Board reviews (IRBs), which may vary from institution to institution.

The Task Force also discussed how research and testing for the drugs to be used by pregnant or lactating women would be prioritized. Both the BPCA and the World Health Organization priority lists were suggested as possible models. Including stakeholders in the process and getting their agreement on the process used and resources needed, is a critical part of this process. One Task Force member noted that the prioritization process may be somewhat different for drugs for use by additional populations than for entirely new drugs under development. Another useful approach might be to create two categories for prioritization – the first for pregnancy- and lactation-specific conditions that need to be treated, but for which there are no currently approved drugs, and the second for conditions for which treatments exist, but have not yet been adequately evaluated in pregnant or lactating women. The Working Group agreed that it is feasible to request drug sponsors to have a pregnancy/lactation study plan in place for new drug approvals once those drugs have been prioritized for study.

The Working Group acknowledged that there is still risk involved in the Vaccine Injury Compensation Program, but that the risk is better informed, which led to a discussion about what is sufficient evidence. Several participants requested that as a drug is being tested, it be followed through the stages of pregnancy and lactation.

Working Group 3 – Communication

Drs. Fabiyi and Vasisht presented the findings of Working Group 3, which had been charged with implementation steps for PRGLAC Recommendations 5, 6, and 13.

Rec. 5 – Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women.

The Communication Working Group suggested that NICHD lead the public awareness campaign recommended in Recommendation 5 of the 2018 PRGLAC report. However, NICHD would not lead this on its own; a specific call to action should be made to include the many stakeholders with a commitment to increasing the number of studies that include pregnant and lactating women. In addition, the point was raised that there should be a balance of considerations about the best way to spend scarce research dollars. One specific need is to make clinicians aware of such studies, and to find ways to encourage them to ask their patients to consider enrolling in clinical trials and to participate in registries of the therapeutics they are using. The Working Group recognized that to conduct a public awareness campaign on the scale needed to change behavior, additional funding would probably be required.

Rec. 6 – Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant women and lactating women.

As a more specific directive to carry out Recommendation 6, the group stated that NICHD should develop a list of available research opportunities as part of a campaign to reach out to health care providers about encouraging pregnant and lactating women to participate in research. An up-to-date, complete resource that would allow health care providers to access clinical trial information should be provided as part of this effort. The group also suggested that various means might be used to determine the barriers to health care providers having discussions with their patients about potential participation in clinical trials. Stakeholder participation in this formative research is critical. Once those are identified, the group thought that some incentives for health care providers to hold these discussions (opportunities for Continuing Education Units, etc.) would be helpful.

Rec. 13 – Optimize registries for pregnancy and lactation.

The Working Group recognized that information collected through registry studies about therapeutics used by pregnant and lactating women would provide invaluable information to be used by both health care providers and researchers. These registries would be in addition to those required by the FDA for specific products and could include collaborations across HHS. The group suggested exploring public-private partnerships to support pregnancy and lactation

registries, including their maintenance, and that the development and support of incentives might encourage participation. Overall policies for registry governance should be established.

Discussion

The Task Force first discussed Recommendation 13, noting that many patients and practitioners are not aware of registries that may be enrolling participants. Some overarching cautions were expressed about the historical distrust in research among some population groups that must be overcome to achieve equitable participation. Specific strategies to reach out to these groups, such as African American or American Indian/Alaska Native women, should be developed. Dr. Bianchi noted that equity is a cross-cutting theme that should permeate the implementation plan.

Members of the Task Force suggested a landscape assessment to determine what information (e.g., recruitment information, enrollment status, interim results) is currently available in existing pregnancy registry websites, such as the list of registries kept by the FDA Office of Women's Health, those on the NIH website, and clinicaltrials.gov. If industry is already required to post clinical trial information and results in clinicaltrials.gov and other places, sponsors might be concerned about requirements for an additional registry website. Existing registry websites may not make information available in a format that a clinician, pregnant or lactating woman can use. In addition, registries may use different definitions that make comparison difficult. Several people noted that the European initiative, ConcePTION, is also working on how to make registry information more accessible. One approach would be to make registries more disease/condition-based instead of based on specific therapeutics. Currently, the FDA does not have the authority to require manufacturers to collaborate on an existing registry. In addition, some discussion is needed on when a registry should be closed.

The Task Force seemed to be in general agreement with the Working Group's suggestions regarding Recommendation 5 but discussed several expansions that might be necessary for full inclusion of all populations of pregnant and lactating women. Stakeholder groups that had not been specifically called out in the presentation should include doulas, childbirth educators, and pediatricians. One suggestion was made to engage insurance carriers and Medicaid to learn how to reach their consumers. Materials that are part of the campaign should be multi-lingual. Elevating the entire effort to the HHS level might allow a broader reach for the campaign, possibly beginning with the current trans-HHS effort on maternal mortality.

Regarding Recommendation 6, the Task Force noted that the ConcePTION initiative is developing modules to reach out to health care providers, translating them for the EU member countries. Dr. Bianchi noted again her recent meeting with the project leads, and that there is alignment between ConcePTION and PRGLAC. Task Force members suggested reaching out to health care providers through their professional societies and to consumers through organizations such as the March of Dimes and sites such as http://www.baby.com, noting that the approaches to these groups might be somewhat different. Some suggested more specifically evaluating which health care providers might have more time to talk with pregnant and lactating women about research opportunities, and even then, incentives (different for health care providers and for women) might still be more effective than education alone. However, unlike industry, a government-funded researcher is unlikely to have the funds to pay a woman to participate in a study. Separate appointments to discuss research might be needed. Another suggestion was to

note in a patient's electronic medical record whether she is taking a medication; this would work best if working through a large managed care provider. If working with government entities, the Task Force was reminded to include both the Departments of Defense and Veterans Affairs, because they have excellent databases on reproductive health care utilization and outcomes, and specifically, DoD has a large database over an extended timeframe on women of reproductive age and birth outcomes. .

Working Group 2 – Regulatory

Drs. Avenevoli and Bok presented the findings of Working Group 2, which had been charged with implementation steps for PRGLAC Recommendations 1, 4, and 7.

Rec. 1 – Include and integrate pregnant women and lactating women in the clinical research agenda.

Dr. Avenevoli acknowledged that some of the recommendations included in Recommendation 1 have already been completed, such as the deletion of pregnant women as an example of a vulnerable population in the federal regulations protecting human subjects (the "Common Rule"). Individual Institutional Review Boards (IRBs) will decide whether pregnant women should be included in the study they are reviewing, and if so, whether extra protections should be provided. The Working Group suggested that guidance offered to IRBs should be updated to reflect the revised regulations.

The Working Group also made several suggestions about interim research that might be necessary to understand subsets of studies that may require additional parental consent and stated that the NICHD's Obstetric and Pediatric Pharmacology and Therapeutics Branch might support work to fill these gaps. Harmonization with the FDA and across HHS is optimal.

Rec. 4 – Remove regulatory barriers to research in pregnant women.

Similarly, for Recommendation 4, the Working Group suggested working with the HHS Office of Human Research Protections to gather necessary information – such as the impact on research - to inform any modification to the HHS regulations (45 CFR part 46, subpart B, Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) to only require the pregnant woman's consent for participation in studies where the prospect of direct benefit is solely for the fetus (replacing the requirement for consent of both biological parents). This information would inform a more narrowly targeted revision to the subpart B regulations. Additional models showing drug concentrations in pregnant and lactating women would be useful, and the group suggested again working with the EU's ConcePTION project.

Rec. 7 – Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women.

Dr. Bok acknowledged that the Working Group's discussions had included liability issues throughout. The working group did not feel they had adequate legal and other expertise to make concrete recommendations, and recognized that PRGLAC is unlikely to solve the entire liability

issue in the U.S. They reviewed existing government models, such as the Vaccine Injury Compensation Program (VICP), BPCA, and the new NASEM Birth Settings study to evaluate potential feasibility and costs of different approaches, taking the most useful aspects of each. Another idea is to create a targeted incentive program through the FDA to require additional data on pregnant and lactating women, possibly through post-approval studies. More information/research is still needed on the mechanisms of teratogenicity to develop new approaches to drug development for these populations.

Discussion

The Task Force began by discussing Recommendation 7, with several members noting that the pathways for research on therapeutics used during pregnancy may differ from those used while lactating. Similarly, the HHS regulations focus on ethical issues around research during pregnancy, with little or no mention of research conducted with women who are breastfeeding. Dr. Bianchi noted that the EU ConcePTION project is taking the approach of focusing more on research during lactation (e.g. a breastmilk biobank, etc.)

Overall, Task Force members agreed that some fundamental information about the mechanisms of teratogenicity is required before creating a federal program, and that the timeline presented was reasonable. In addition, the cost of a new program must be considered; a comment was made that while pediatric research is spread across the NIH Institutes and Centers (so that the cost of the BPCA program can be similarly shared), pregnancy-related research is largely supported by NICHD. Other options for encouraging research also could be explored, such as research tax credits, similar to those created by the federal Orphan Drug Act. Task Force members were reminded of the major differences between supporting research for on- and off-patent drugs, and that it would be most useful to break this into separate goals.

The discussion around Recommendation 1 focused on re-educating IRBs regarding the inclusion of pregnant and lactating women in clinical research in light of the revisions to the Common Rule regulations, whether they are centralized, part of an academic research institution, or independent. IRBs may still be concerned that they would be blamed for any adverse outcomes in a trial that includes pregnant women. Some Task Force members suggested working with commercial IRBs that have implemented the regulatory revisions, using their training modules as guidance. These educational materials could also be shared with international IRBs.

Task Force members generally supported the steps recommended by the working group to begin to implement Recommendation 4, particularly working closely with OHRP to explore the possibility of opening up another section of the subpart B regulations to allow pregnant women to consent on their own to participation in research, rather than (in some circumstances) requiring two-parent consent. More information is needed about how to make the narrowest change to the minimal risk standard. Some members also called for additional research using animal models for teratogenicity, which could help establish an evidence base for these steps.

Working Group 1 – Research/Training

Dr. Bremer presented the findings of Working Group 1, which had been charged with implementation steps for PRGLAC Recommendations 2, 3, 8, and 11.

Rec. 2 – Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women.

Members of the Working Group stated that the majority of drugs used by pregnant and lactating women are not teratogenic. Consequently, PRGLAC should try to help change the medical and social cultures to emphasize the potentially negative effects on the pregnant or lactating women and their offspring if necessary treatment of the woman were to be withheld. Several suggestions were offered, such as using existing clinical research networks to facilitate this research, and to make more use of existing data to inform future studies. The Working Group also encouraged various types of collaborations, including adding more women to existing registries, creating incentives for health care providers to encourage their patients to participate in studies, and developing and utilizing alternative study designs, common data elements, and outcome measures to facilitate clinical studies. Due to the time needed to recruit participants into large clinical trials, targeted funding opportunities that would permit longer term awards in the near term might be helpful. The working group estimated that five phase III clinical trials could cost about $40 million, with an additional $5 million for up to 10 mechanistic studies.

Rec. 3 – Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics.

Working Group 1 strongly advocated for more training in obstetric and lactation pharmacology and suggested several mechanisms that might help develop the pharmacologic workforce. Support could take several forms, such as a "virtual college of mentors," online training opportunities/credentialing, training support within existing federally funded research networks, and collaborations with professional societies or industry partnerships to support fellowships.

Rec. 8 – Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model.

The Working Group recommended that the NIH portion of the BPCA program be analyzed for any lessons learned over the past 20 years. One clear lesson learned is that to efficiently and effectively conduct research in pregnant and lactating women, similar to conducting research in pediatric populations, some infrastructure is necessary to allow clinical trials to recruit sufficiently, especially for off-patent drugs. In addition, drug testing should be coordinated throughout pregnancy and lactation since a woman's physiology and metabolism change across those periods, potentially affecting a drug's pharmacokinetics and pharmacodynamics. To minimize human exposure, the Group suggested additional support for technology development, such as "tissue on a chip," and that a pregnancy registry for generic drugs be established. Even if existing networks are utilized, full implementation may require additional resources. The working group estimated that it would cost about $16 – 20 million to establish or expand the necessary clinical trials infrastructure to achieve the objectives of the recommendation. Because not all therapeutics can be studied at once, the Working Group also recommended that a prioritization process, similar to that established by the NIH BPCA program, be used to identify which studies should be conducted first.

Rec. 11 – Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women.

Working Group 1 supported the approach of adding sites to existing clinical research networks to take advantage of established infrastructure and to broaden the populations of pregnant and lactating women who might participate in clinical trials. The Pediatric Trials Network was cited as an example. The group also suggested streamlining processes for collaborations across industry, similar to the Innovative Medicines Initiative sponsored by the EU. Some particular unmet needs include outcome measures for long-term follow-up of infants exposed to therapeutics *in utero* or during breastfeeding, and improving the usability of current drug registries, including identifying why the registry may be unsuccessful.

Discussion

During the discussion on Recommendation 2, Task Force members suggested that adaptive platform trials might be an appropriate mechanism to use, both for studies on pregnancy and lactation. Several people reiterated the need to educate and emphasize that there is a risk of not breastfeeding, even if a woman is taking a needed medication. Similar to differing metabolism during stages of pregnancy, studies should consider varying levels of drug transfer during different stages of lactation. One suggestion was made that research on therapeutics for both drugs used in pregnancy-related conditions and drugs that may be used in pregnancy should be conducted along the entire continuum of pregnancy and lactation, including drugs and drug metabolites crossing into the placenta and breastmilk.

Task Force members provided additional input on Recommendation 3. Dr. Bremer provided additional information on different types of training and career development grants. The Group suggested including additional clinicians in research who might be interacting with pregnant or lactating women, such as advanced practice nurses, and non-clinician investigators. Others suggested that, if the Task Force wishes to encourage mentoring, funders need to address the issues of time requirements and how to offset clinical revenue that may be lost while investigators are engaged in mentoring and research endeavors.

Regarding implementation of Recommendations 8 and 11, Task Force members expressed concern about how a new program/infrastructure for funding research on therapeutics used by pregnant and lactating women could be funded. Suggestions were made to create public-private partnerships with industry and other stakeholders (government and non-governmental). If using the NIH BPCA program as a model, recognizing that pregnancy related research is not supported across NIH, an institute supporting research on the underlying health condition could help fund the pregnancy related research. The inclusion of pregnant and lactating women from the start would be helpful, as would the development of biomarkers for both children and adults.

Summary – Dr. Bianchi

Dr. Bianchi summarized the major themes she heard during the meeting's presentations and discussions:

- PRGLAC should learn from BPCA/PREA's experience with pediatric drug prioritization, both what has worked as well as what has not worked.

- A more developed infrastructure for prioritizing drugs used by pregnant and lactating women for further study is needed.
- Further input from individuals with bioethics expertise is needed regarding any potential revisions of the 45 CFR part 46 Subpart B HHS regulations. The NIH Clinical Center's Bioethics Department would be a good resource.
- More preclinical models (e.g. placental or mammary "tissue on a chip") are needed to further this research, but there is no clear lead for this.
- Funding is a core issue; a public-private partnership, possibly working through the Foundation for the NIH, might be one avenue for expanding research opportunities.
- The NIH Clinical Center could provide another opportunity. Currently, no studies involving pregnant women are taking place there. It might work to begin with studies involving lactating women, and work toward changing the culture.
- The Bill and Melinda Gates Foundation is very interested in human milk research.
- We should learn from the EU's ConcePTION project.
- We need to build a lay person-friendly clinical trials site.

The Task Force members commented on these themes. The Task Force will need to work closely with partner organizations to communicate messages regarding PRGLAC implementation. Several cautioned that implementation should not be an unfunded mandate.

A few members stated that lactation studies might be easier to enroll and less costly than studies involving pregnant women, and thus, a good place to begin to implement PRGLAC's goals. How to incentivize industry to include pregnant women in their studies is still a critical question, which then leads to the question of whether to begin by studying off-patent drugs rather than new drugs. While some in industry are conducting this research, liability remains a major concern.

Dr. Bianchi asked the group for additional topics that had not been discussed. Responses included pain management, improved devices such as breast pumps, health disparities/equity and access to studies that are funded, and the use of registries.

Next Steps

Dr. Bianchi acknowledged that several of the Working Groups' ideas overlap. An executive summary/overview will be written for the implementation plan that will identify cross-cutting topics. Task Force members suggested that the plan clearly identify action items, prioritizing those that can be executed more quickly.

Write ups of the implementation steps for each recommendation will be shared with the entire Task Force for comment. Those comments will be incorporated, and an entire draft plan will be sent to the Task Force for a second round of comments. The next meeting will be held by webinar to go over them. The goal is to submit the plan to the Secretary before the end of the fiscal year.

Dr. Bianchi thanked everyone for a productive meeting, and adjourned.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Lisa Kaeser, J.D.
Executive Secretary, Task Force on Research Specific to Pregnant Women and Lactating Women